US ERA ARCHIVE DOCUMENT

DATA EVALUATION RECORD § 71-2(B) -- WATERFOWL DIETARY LC₅₀ TEST

1. <u>CHEMICAL</u>: Cloquintocet-mexyl <u>PC Code No.</u>: 999999

2. TEST MATERIAL: CGA-185072 Purity: 91.6%

3. CITATION

Authors: B.Hakin, A.J.Norman, M.H.Rodgers, A.Anderson, and

I.S.Dawe.

<u>Title</u>: The Subacute Dietary Toxicity of CGA-185072 to the

Mallard duck.

Study Completion Date: January 14, 1989

<u>Laboratory</u>: Huntingdon Research Centre, Ltd.

P.O. Box 2

Huntingdon, Cambridgeshire, PE18 6ES,

Date: 12/1/28

Date: 12/25/98

England

Sponsor: Novartis Crop Protection, Inc.

P.O. Box 18300

Greensboro, NC 27419

Laboratory Report ID: CBG 470/89102

MRID No.: 443874-08

4. **REVIEWED BY:** Stephen Carey, Biologist, EFED, ERBIII

5. APPROVED BY: Harry Craven, EFED, ERBIII

Signature: Stephen Comes

6. STUDY PARAMETERS

Signature:

Scientific Name of Test Organism: Anas platyrhynchos Age of Test Organisms at Test Initiation: 10 days old Definitive Study Duration: 3-day pre-treatment period

Henry Croven

5-day treatment period

3-day post-treatment period

2008638

7. CONCLUSIONS:

Results Synopsis

LC₅₀: >5310 ppm ai NOEL: 5310 ppm ai 95% C.I.: N/A Probit Slope: N/A

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale: N/A

C. Repairability: N/A

9. **GUIDELINE DEVIATIONS**

1. N/A

10. <u>SUBMISSION PURPOSE</u>:

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information				
Species: A wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>).	Anas platyrhýnchos				
Age at beginning of test: 5-10 days old (preferably 5).	10 days old				
Supplier	Mr. John Coles The County Game Farms, Home Farm Hothfield, Ashford, Kent				

Guideline Criteria	Reported Information
Chicks appeared healthy and did not have excessive mortality before the test?	Yes
Acclimation period: As long as possible.	7 days

B. Test System

Guideline Criteria	Reported Information				
Pen size: about 70 x 100 x 24 cm	80 x 36 x 30 cm				
Brooder temperature: about 35°C (95°F)	Not Reported				
Room temperature: 22-27°C (71-81°F)	28-31°C				
Relative humidity: 30-80%	47%				
Adequate ventilation?	Yes				
Photoperiod Minimum of 14 h of light.	Not Reported				
Diet: A commercial waterfowl feed.	Basal diet				

C. Test Design

	Guideline	Criteria	Reported Information	
F	Range finding test?		No	

Guideline Criteria	Reported Information				
Definitive Test Nominal concentrations: Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless $LC_{50} > 5000$ ppm.	$LC_{50} > 5200$ ppm. Concentrations: Control, 163, 325, 650, 1300, 2600, and 5200 ppm.				
Controls: Control group tested with diet containing the maximum amount of vehicle used in treated diets?	Not Reported				
Number of birds per group: 10 (strongly recommended)	10				
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Corn oil				
Vehicle amount (% of diet by weight): Not more than 2%.	Not Reported				
Test durations: 5 days with treated feed and at least 3 days observation with "clean" feed.	5-day treatment period 3-day post-treatment period				
No mortality during last 72 hr of observations?	No				

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Body weights measured at beginning and end?	Yes

Guideline Criteria	Reported Information					
Estimated consumption per pen reported for pretreatment, treatment, and observation periods?	Yes					
Control Mortality: / Not more than 10%	0%					
Raw data included?	Yes					
Signs of toxicity (if any) were described?	No					

Mortality

Conc. (ppm)			Cumulative Number of Dead								
	Mean Nominal Measured		No. of			Day	y of S	tudy			
Group		Birds	1	2	3	4	5	6	7	8	
Control	0	ND	10	0	0	0	0	0	0	0	0
4	163	161	10	0	0	0	0	0	0	0	0
5	325	317	10	Ó	0	0	0	0	0	0	0
6	650	642	10	0	0	0	0	0	0	0	0
7	1300	1240	10	0	0	0	0	0	0	0	0
8	2600	2590	10	0	0	0	0	0	0	0	0
9	5200	5310	10	0	0	0	0	0	0	0	0

Other Significant Results: The food consumption and body weight gain was unaffected in the study.

Statistical Results

Statistical Method: Visual estimation

LC₅₀: >5200 ppm 95% C.I.: N/A NOEL: 5200 ppm Probit Slope: N/A

13. Verification of Statistical Results

Statistical Method: Visual estimation

LC₅₀: >5310 ppm NOEL >5310 ppm

14. REVIEWER'S COMMENTS: This study is scientifically sound and fulfills the guideline requirements for a subacute dietary toxicity test using mallard duck. Based on mean measured concentrations, the 5-day LC50 was determined to be >5310 ppm, which classifies CGA-185072 as practically non-toxic to the duck. The NOEC was determined to be 5310 ppm. Data on the test organism's brooder temperature, photoperiod, test with diet containing the maximum amount of vehicle used in treated diets, and vehicle amount are not reported in the study. Although, this is not crucial since there was no mortality reported in this study. This study is classified as **core**.